

**NAPHAZOLINE HCl AND PHENIRAMINE MALEATE- naphazoline hydrochloride ,  
pheniramine maleate solution/ drops  
Altaire Pharmaceuticals Inc.**

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**Naphazoline HCl 0.027% & Pheniramine Maleate 0.315% Ophthalmic Solution, USP**

Active Ingredients

Naphazoline Hydrochloride (0.027%)

Pheniramine Maleate (0.315%)

Purpose

Redness Reliever

Antihistamine

Uses: temporarily relieves itching and redness caused by pollen, ragweed, grass, animal hair and dander.

Warnings: if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a physician. Do not use in children under 6 years of age unless directed by a physician. If this solution changes color or becomes cloudy, do not use. Overuse of this product may produce increased redness of the eye.

If you are sensitive to any ingredient in this product, do not use. To avoid contamination, do not touch tip of container to any surface. Replace cap after using.

Do not use if imprinted seal on cap is torn, broken or missing, or if imprinted seals on top and bottom flaps are not intact and completely legible.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- trouble urinating due to enlarged prostate gland
- narrow angle glaucoma

Remove contact lenses before using.

Stop use and ask a doctor if you experience: eye pain, changes in vision, redness or irritation of the eye that worsens or persists for more than 72 hours. Overuse of this product may produce increased redness of the eye. Pupils may become enlarged temporarily. You may experience a brief tingling sensation after putting drops in eyes.

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Accidental oral ingestion in infants and children may lead to coma and marked reduction in body temperature.

Directions:

Adults and children 6 years of age and older: instill 1 or 2 drops in affected eye(s) up to 4 times daily.

Children under 6 years: ask a doctor.

Store at room temperature 20 degrees - 25 degrees C ( 68 degrees - 77 degrees F).

Protect from light.

Use before expiration date marked on the carton or bottle.

Available in 15mL NDC 59390-177-13 and 30 mL NDC 59390-177-18

Inactive ingredients

benzalkonium chloride 0.01%, boric acid, edetate disodium 0.1%, hypromellose, purified water, sodium borate, and sodium chloride.

Questions or comments

Call (631) 722-5988 9am - 5pm EST Monday - Friday

Manufactured by:

Altaire Pharmaceuticals, Inc.

Aquebogue, N.Y. 11931

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Naphazoline HCl 0.027%

and

Pheniramine Maleate 0.315%

Ophthalmic Solution, USP

Eye Allergy Relief

With Antihistamine To Relieve Itching

Itching and Redness Reliever

Eye Drops

0.5 Fl. Oz. (15mL)

NDC 59390-177-13	
	
<b>DO NOT USE IF IMPRINTED SEAL ON CAP IS TORN, BROKEN OR MISSING.</b>	
<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Naphazoline	
Hydrochloride (0.027%)	Redness Reliever
Pheniramine Maleate (0.315%)	Antihistamine
<b>Uses:</b> temporarily relieves itching and redness caused by pollen, ragweed, grass, animal hair and dander.	
<b>Directions:</b> Adults and children 6 years of age and older: instill 1 or 2 drops in affected eye(s) up to 4 times daily. Children under 6 years: ask a doctor.	
<b>Warnings:</b> if you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a physician. Do not use in children under 6 years of age unless directed by a physician. If this solution changes color or becomes cloudy, do not use. Overuse of this product may produce increased redness of the eye.	
<b>Keep out of the reach of children.</b>	
<b>Remove contact lenses before using.</b>	
See Carton for additional WARNINGS.	
Store at room temperature 20°-25°C (68°-77°F). Protect from light.	
<b>Questions or comments</b>	
Call (631) 722-5988 9am - 5pm EST Monday - Friday	
Manufactured by:	 ALTAIRE Pharmaceuticals, Inc. Aquebogue, N.Y. 11931
R0209	



## NAPHAZOLINE HCl AND PHENIRAMINE MALEATE

naphazoline hydrochloride , pheniramine maleate solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59390-177
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	0.27 mg in 1 mL
PHENIRAMINE MALEATE (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9ZZ6M)	PHENIRAMINE MALEATE	3.15 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59390-177-13	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/06/2010	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078208	10/06/2010	

**Labeler** - Altaire Pharmaceuticals Inc. (786790378)

### Establishment

Name	Address	ID/FEI	Business Operations
Altaire Pharmaceuticals Inc.		786790378	manufacture(59390-177)

Revised: 12/2020

Altaire Pharmaceuticals Inc.